Notice of Allowability	Application No.	Applicant(s)	
	10/672,876	DONOVAN, STEPHEN	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *8/4/06*.

2. ☒ The allowed claim(s) is/are *1,5 and 13-21*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 5 and 13-21 are pending.

Applicants' amendment and response filed August 4, 2006 is acknowledged. Applicants' response has been fully considered. Claims 1, 13, 17, 19 and 21 have been amended. Therefore, claims 1, 5 and 13-21 are examined.

Withdrawn Claim Objection

2. The previous objection to claims 16 and 20, is withdrawn in view of applicants' amendment to the claim in the amendment filed August 4, 2006.

Withdrawn Claim Rejection- 35 USC § 103

3. The previous rejection of claims 1, 5, 13-15, 17-19 and 21 under 35 U.S.C. 103(a) as being unpatentable over Lewis *et al.* (Production of Botulinum Toxin Vol. 53, pages 213-230 (1947)), is withdrawn in view of applicants' amendment to the claim, and applicant's response at page 4 of the amendment filed August 4, 2006.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Stephen Donovan on October 10, 2006.

Examiner's Amendment to the Claims:

Claims 1, 13, 15-17 and 19-21 have been amended as follows:

1. (Currently amended) A method for obtaining a biologically active botulinum toxin, comprising the steps of:

(a) providing a fermentation medium which is free of an animal product;

(b) culturing a Clostridium botulinum bacterium in the fermentation medium under conditions which permit production of a botulinum toxin, and;

(c) recovering a biologically active botulinum toxin from the fermentation medium,

wherein the fermentation medium comprises a protein product obtained from yeast or from a vegetable, and wherein the vegetable is selected from the group consisting of ~~a~~ soy, malt and corn.

13. (currently amended) A method for making a substantially animal product free pharmaceutical composition in which the active ingredient is a botulinum toxin, the method comprising the steps of:

(a) obtaining a biologically active botulinum toxin by~~;~~:

(i) providing a fermentation medium which is free of an animal product;

(ii) culturing a Clostridium botulinum bacterium in the fermentation medium under conditions which permit production of a botulinum toxin, and;

(iii) recovering a biologically active botulinum toxin from the fermentation medium;

(b) formulating the botulinum toxin with a suitable excipient, thereby making a substantially animal product free pharmaceutical composition in which the active ingredient is a botulinum toxin,

wherein the fermentation medium comprises a protein product obtained from yeast or from a vegetable, and wherein the vegetable is selected from the group consisting of ~~a~~ soy, malt and corn.

15. (currently amended) The method of claim 1, wherein the botulinum toxin is ~~a~~ botulinum toxin types A.

16. (currently amended) The method of claim 1, wherein the botulinum toxin is ~~a~~ further purified ~~botulinum toxin~~.

17. (currently amended) A method for obtaining a biologically active botulinum toxin type A, the method comprising the steps of:
(a) providing a fermentation medium which is free of an animal product;
(b) culturing a Clostridium botulinum type A bacterium in the fermentation medium under conditions which permit production of a botulinum toxin type A, and;
(c) recovering a biologically active botulinum toxin type A from the fermentation medium, wherein the fermentation medium comprises a protein product obtained from yeast or from a vegetable, and wherein the vegetable is selected from the group consisting of ~~a~~ soy, malt and corn.

19. (currently amended) The method of claim 13, wherein the botulinum toxin is ~~a~~ botulinum toxin type A.

20. (currently amended) The method of claim 13, wherein the botulinum toxin is ~~a~~ further purified ~~botulinum toxin~~.

21. (currently amended) A method for making an animal product free pharmaceutical composition in which the active ingredient is a botulinum toxin type A, the method comprising the steps of:
(a) obtaining a biologically active botulinum toxin type A by~~;~~:

(i) providing a fermentation medium which is free of an animal product;

(ii) culturing a Clostridium botulinum type A bacterium in the fermentation medium under conditions which permit production of a botulinum toxin type A, and;

(iii) recovering a biologically active botulinum toxin type A from the fermentation medium;

(b) formulating the botulinum toxin type A with a suitable excipient, thereby making an animal product free pharmaceutical composition in which the active ingredient is a botulinum toxin type A,

wherein the fermentation medium comprises a protein product obtained from yeast or from a vegetable, and wherein the vegetable is selected from the group consisting of a soy, malt and corn.

The following is an Examiner's Statement of Reasons for Allowance: The following reference appears to be the closest art to the claimed invention. Lewis *et al.* (Production of Botulinum Toxin Vol. 53, pages 213-230 (1947)) teach that botulinum toxin type A can be obtained by culturing "Hall" strain of Clostridial botulinum type A bacterium in the fermentation medium containing less than 1% of animal protein product such as pepticase or casein. However, the reference does not teach or suggest culturing a Clostridial botulinum bacterium in a fermentation medium which is free of an animal product and comprises a protein product obtained from yeast, soy, malt or corn. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner

primary CHIH-MIN KAM PATENT EXAMINER

CMK
October 10, 2006